MGP-104US

Appln. No.: 09/943,687

Amendment Dated September 20, 2004 Reply to Office Action of April 20, 2004

<u>Amendments to the Claims:</u> This listing of claims will replace all prior versions, and listings, of claims in the application

Listing of Claims:

- 1. (Currently Amended) An orally administered pharmaceutical composition comprising <u>a spontaneous emulsion of cyclosporine</u>, ethanol, polyoxyethylene glycerol trioleate, and an oil component.
- 2. (Original) The pharmaceutical composition of claim 1, wherein said cyclosporine is cyclosporine A.
- 3. (Original) The pharmaceutical composition of claim 1, wherein said cyclosporine is present at a concentration from about 5 to about 20% by weight.
- 4. (Original) The pharmaceutical composition of claim 3, wherein said cyclosporine is present at a concentration from about 8 to about 12% by weight.
- 5. (Original) The pharmaceutical composition of claim 3, wherein said cyclosporine is present at a concentration of 10% by weight.
- 6. (Original) The pharmaceutical composition of claim 1, wherein said oil component is ethyl oleate.
- 7. (Original) The pharmaceutical composition of claim 1, wherein said ethanol is present at about 15 to about 40 v/v%.
- 8. (Original) The pharmaceutical composition of claim 7, wherein said ethanol is present at about 15 to about 25 v/v%.
- 9. (Original) The pharmaceutical composition of claim 7, wherein said ethanol is present at 20 v/v%.
- 10. (Original) The pharmaceutical composition of claim 1, wherein said polyoxyethylene glycerol trioleate is present at about 20 to about 50 v/v%.
- 11. (Original) The pharmaceutical composition of claim 1, wherein said oil component is present at about 40 to about 65 v/v%.

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- 12. (Original) The pharmaceutical composition of claim 11, wherein said oil component is present at about 55 to about 65 v/v%.
- 13. (Original) The pharmaceutical composition of claim 11, wherein said oil component is present at 60 v/v%.
- 14. (Currently Amendedl) An orally administered pharmaceutical composition comprising a spontaneous emulsion of cyclosporine, ethanol, polyoxyethylene glycerol trioleate and ethyl oleate in a weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and ethyl oleate of about 5:18:25.9:50.1 to about 15:16:23.1:44.9.
- 15. (Original) The pharmaceutical composition of claim 14, wherein the weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and ethyl oleate is 10:17.1:24.5:47.5.
- 16. (Original) The pharmaceutical composition of claim 15, wherein said composition upon dilution with an aqueous media at a ratio of 1 part composition to 100 parts aqueous media forms a spontaneous emulsion.
- 17. (Original) The pharmaceutical composition of claim 16, wherein said spontaneous emulsion comprises particles having a diameter of 50 to 185 nm.
- 18. (Original) A method of preparing an orally administered pharmaceutical composition comprising the steps of:

dissolving cyclosporine in ethanol to form a solution;

combining polyoxyethylene glycerol trioleate and an oil component with the solution to form a mixture; and

diluting the mixture with an aqueous media to allow formation of a spontaneous emulsion.

19. (Original) The method of claim 18, further comprising the step of gently mixing the diluted mixture to disperse the emulsion.

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- 20. (Original) The method of claim 18, wherein the step of diluting further comprises diluting 1 part of the mixture with 100 parts of aqueous media.
- 21. (Original) The method of claim 18, wherein said oil component is ethyl oleate.
- 22. (Original) The method of claim 18, wherein said cyclosporine is cyclosporine A.
- 23. (Original) The method of claim 18, wherein the cyclosporine is present at a concentration of 10% by weight
- 24. (Original) The method of claim 18, wherein said ethanol is present at about 15 to about 40 v/v%.
- 25. (Original) The method of claim 18, wherein said polyoxyethylene glycerol trioleate is present at about 20 to about 50 v/v%.
- 26. (Original) The method of claim 18, wherein said oil component is present at about 40 to about 65 v/v%.
- 27. (Original) The method of claim 18, wherein said composition comprises cyclosporine, ethanol, polyoxyethylene glycerol trioleate and ethyl oleate in a weight ratio of cyclosporine, pure ethanol, polyoxyethylene glycerol trioleate and ethyl oleate of 10:17.1:24.5:47.5.
- 28. (Original) The method of claim 27, wherein said spontaneous emulsion comprises particles having a diameter of 50 to 185 nm.
- 29. (Original) The method of claim 28, wherein said spontaneous emulsion comprises particles having a diameter of 50 to 150 nm.
- 30. (Original) The method of claim 17, wherein said spontaneous emulsion comprises particles having a diameter of 50 to 150 nm.